

REMARKS

Favorable reconsideration of this application in light of the following discussion is respectfully requested.

Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 are pending. No claims are added, canceled or amended. Therefore, no new matter is introduced.

In the outstanding Office Action, Claims 1, 20, 27, 28, 34, 67 and 69-71 were rejected under 35 U.S.C. § 112, first paragraph; and Claims 1, 3, 20, 27, 28, 34, 67 and 69-71 were rejected under 35 U.S.C. § 103(a) as being unpatentable over unpatentable over Yu (U.S. Patent Application Publication No. 2003/0105496) in view of Salo (U.S. Patent No. 5,728,140).

Initially, the rejection of Claims 1, 20, 27-28, 34, 67 and 69-71 under 35 U.S.C. § 112, first paragraph, as allegedly lacking proper written support in the specification is respectfully traversed.

MPEP § 2163 states that the written description requirement is satisfied when the patent specification describes the claimed invention in sufficient detail such that one of ordinary skill in the art can reasonably conclude that the inventor has possession of the claimed invention. Possession may be shown through description in words, figures, diagrams, etc.¹ If a rejection is to be made under Section 112, the Examiner has the initial burden to establish a *prima facie* case as to why one of ordinary skill in the art would not recognize a description of the claimed invention in the disclosure.² In this regard, MPEP §2163 requires that,

The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the *Wang Labs. V. Toshiba Corp.*, 993 F.2d 858, 865, 26

¹ See MPEP §2163.

² Id.

USPQ2d 1767, 1774 (Fed. Cir. 1993)) and *should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement.* Information which is well known in the art need not be described in detail in the specification. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986). (Emphasis added.)

Therefore, to establish a *prima facie* case under Section 112, first paragraph, analysis of the level of ordinary skill in the art is required in order to establish the specificity required in the disclosure to satisfy the written description requirement. In contrast, the outstanding Office Action merely relies on the conclusory statement that the “claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention,”³ without providing any of the requisite analysis. Indeed, under the proper analysis, the written description is satisfied at least based on the descriptions of pacing only the left ventricle, positioning an electrode in the interventricular septum, and the type of electrode provided in paragraphs 59-62 of the specification. Therefore, it is submitted that Claims 1, 20, 27-28, 34, 67 and 69-71 satisfy the written description requirement, and that the rejection of these claims under 35 U.S.C. §112, first paragraph, as failing the written description requirement is improper and should be withdrawn.

With regard to the rejection of Claims 1, 20, 27-28, 34, 67 and 69-71 under 35 U.S.C. § 112, first paragraph, as not being enabled, this rejection is also respectfully traversed as an enabling description can be found at least at paragraphs 59-62. For example, placing a ventricular pacing electrode in the interventricular septum is described. Placement of the electrode is also illustrated relative to the other structures in the heart in Fig. 7.

³ See the outstanding Office Action at page 2.

The outstanding Office Action asserts that enablement of the claims is lacking because the specification does not describe a particular location where an electrode is to be placed to pace only a left ventricle.⁴ However, a description is enabling if one of ordinary skill in the art can make and use the claimed invention without undue experimentation.⁵ In this regard MPEP § 2164.01 provides,

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ 2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 2984, 504, 190 USPQ 214, (CCPA 1976).

Further, to determine whether any necessary experimentation is undue requires analysis of several factors including the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention.⁶ However, the outstanding Office Action lacks any such analysis. It is submitted that under the analysis of MPEP §2164, the enablement requirement is met as one of ordinary skill in the art would be able to make and use the invention without undue experimentation based on at least paragraphs 59-62 of the disclosure as originally filed, as well as Fig. 7. As such, Claims 1, 20, 27, 28, 34, 67 and 69-71 satisfy the enablement requirement, and it is respectfully requested that the rejection of these claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

Turning to the rejection of Claims 1, 3, 20, 27-28, 34, 67 and 69-71 as being unpatentable over Yu in view of Salo, this rejection is also respectfully traversed.

⁴ See the outstanding Office Action at page 3.

⁵ See MPEP § 2164.01.

⁶ See MPEP § 2164.01(a).

Claim 1 is directed to a method of configuring signaling locations within a heart for performing intra chamber resynchronization that includes:

positioning signaling electrodes to deliver stimulation to only a left ventricle of the heart, the signaling electrodes being positioned along a first and second axis interior to the heart, the second axis extending within the left ventricle to position at least one first signaling electrode of the signaling electrodes thereabout, the first axis extending into a right ventricular septum of the heart to position at least one second signaling electrode of the signaling electrodes at a position in the right ventricular septum to deliver stimulation to the left ventricle; and

delivering, to the left ventricle, stimulation via the at least one first and second signaling electrodes for performing the intrachamber recynchronization.

Thus, Claim 1 defines a method of positioning signaling electrodes to deliver stimulation to only a left ventricle of the heart where at least one electrode is positioned at a position in the right ventricular septum to deliver stimulation to the left ventricle.

In contrast, Yu describes a method of synchronization of ventricular wall contractions using direct mechanical measurements.⁷ Yu illustrates an accelerometer (142) and an electrode (140) positioned at a free wall of the left ventricle (112), while another accelerometer (150) and electrode (148) are positioned at a free wall of the right ventricle (108).⁸ A third accelerometer (146) and electrode (144) are positioned within the right ventricle adjacent to the septum (109).⁹ In operation, Yu describes that the accelerometers (142, 146 and 150) move with corresponding ventricular wall contractions and generate corresponding signals, which are then used by a processing module (198) to generate stimulating signals delivered to the electrodes (148, 144 and 140).¹⁰ Yu describes that because cardiac resynchronization seeks to stimulate a mechanical response in the heart,

⁷ Yu at paragraph 13.

⁸ Yu at paragraph 27; see also Figure 3.

⁹ Yu at paragraph 27; see also Figure 3.

¹⁰ Yu at paragraphs 32-33.

direct mechanical measurement is superior to indirect measurement through electrical activity.¹¹

The outstanding Office Action acknowledges that Yu does not disclose stimulating only the left ventricle, and combines Yu with Salo to remedy this deficiency. However, Salo describes a tissue-piercing electrode embedded within the interventricular septum, just below the surface of the left ventricular wall of the septum, in order to pace the left ventricle without actually placing an electrode in the left ventricle itself.¹² Salo describes this electrode placement to avoid inserting an electrode in the left ventricle because of the risk of a thrombus, and to avoid an intercostal placement of an electrode along the left ventricle to minimize the risk of infection.¹³ In contrast, Yu requires electrode placements in both ventricles in order to directly monitor contractions using accelerometers.¹⁴ Thus, Yu and Salo present divergent teachings, which could only have been combined through impermissible hindsight reconstruction based upon Applicant's disclosure. Yet, as the Office is no doubt aware:

Knowledge of applicant's disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.¹⁵ (Emphasis added.)

Therefore, it is submitted that the pending claims of this application are not rendered obvious by the combination of Yu with Salo as these references have been improperly combined based upon impermissible hindsight reconstruction. As such, Claim 1 and any claim depending therefrom is believed to be in condition for allowance.

¹¹ Yu at paragraph 10.

¹² Salo at column 1, lines 45-57.

¹³ Salo at column 1, lines 25-37.

¹⁴ Yu at paragraph 10; see also Fig. 3.

¹⁵ MPEP § 2142

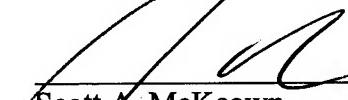
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Furthermore, Claim 67 recites features substantially similar to those recited in Claim 1 and is believed to be in condition for allowance, together with any claim depending therefrom, for substantially similar reasons. Accordingly, it is respectfully requested that the rejection of Claims 1, 3, 20, 27-28, 34, 67 and 69-71 under 35 U.S.C. § 103(a) be withdrawn.

For the reasons discussed above, no further issues are believed to be outstanding in the present application, and the present application is believed to be in condition for formal allowance. Therefore, a Notice of Allowance for Claims 1, 3, 20, 27-28, 34, 67 and 69-71 is earnestly solicited.

Respectfully submitted,

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